



Translation of the Original Operating Instructions

Ultrasonic Nebulizer

HICO-ULTRASONAT 810



CE 0124



seit 1945

HIRTZ & Co. KG

Bonner Str. 180
50968 Köln/Germany

Phone: +49 (0) 2 21 / 37 67 8 – 0

Fax: +49 (0) 2 21 / 37 67 8 – 85

E-mail: hirtz@hico.de

Internet: www.hico.de

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1 General

Please read the information in this manual to become acquainted with the HICO-ULTRASONAT 810 as quickly as possible to be able to utilize its functions to the full extent.

1.1 Information about this instruction manual

These operating instructions are part of the HICO-ULTRASONAT 810 (hereafter referred to as unit) and contains important notes concerning commissioning, safety, intended use as well as care and maintenance of the unit.

All illustrations and drawings in these operating instructions serve the purpose of general understanding and are not relevant with respect to design details.

These operating instructions must be available at all times, preferably near the unit. They must be read by any person involved in the:

- commissioning,
- operation,
- cleaning,
- maintenance,
- trouble shooting

of the unit.

1.2 Warning notes

The following warning notes are used in these operating instructions:

▲ DANGER

A warning note of this danger level identifies an imminent dangerous situation.

Not avoiding this dangerous situation will cause severe injury or even death.

- ▶ Follow the instructions given in this warning note to avoid the danger of death or severe injury to persons.

▲ WARNING

A warning note of this danger level identifies a possibly dangerous situation.

Not avoiding this dangerous situation can lead to severe injuries.

- ▶ Follow the instructions in this warning note to avoid the risk of injuries to persons.

▲ CAUTION

A warning note of this danger level identifies a possibly dangerous situation.

Not avoiding this dangerous situation can lead to minor or moderate injuries.

- ▶ Follow the instructions in this warning note to avoid the risk of injuries to persons.

CAUTION

A warning note of this danger level identifies the possibility of material damage.

Not avoiding this situation can lead to material damage.

- Follow the instructions in this warning note to avoid the risk of material damage.

NOTE

A note highlights additional information to assist in working with the unit.

1.3 Limitation of liability

All technical information, data and notes on installation, operation and care contained in this manual were up-to-date at the date of printing and have been entered to the best of our knowledge under due consideration of our previous experience and knowledge.

No claims can be deduced from the information, illustrations and descriptions in this instruction manual.

The manufacturer will not assume liability for damaged resulting from:

- disregarding these instructions
- unintended use
- unprofessional repairs
- technical modifications
- use of non-permitted spare parts
- unauthorized conversions and changes

Translations are made to the best of our knowledge. We do not assume liability for translation mistakes, even if the translation was made by us or ordered by us. Only the original German text is binding.

1.4 Copyright law

This documentation is protected by copyright law.

All rights, also the rights for photo-mechanical reproduction, copying and distribution by means of special methods (e.g. data processing, data carrier and data networks), even in parts, remain reserved by HIRTZ & Co. KG.

Subject to changes in contents and technical modifications.

1.5 Manufacturer's address

HIRTZ & Co. KG

Bonner Str. 180

50968 Köln/Germany

Phone: +49 (0)2 21 / 3 76 78-0

Fax: : +49 (0)2 21 / 3 76 78-85

E-mail: hirtz@hico.de

2 Safety

This chapter contains important safety notes for work with this unit. This unit complies with the specified safety regulations. However, improper use can lead to personal injury or material damage.

2.1 Intended use

This unit is solely intended for the nebulization of fluids in clinical and therapeutic applications for the treatment of the respiratory tract on a patient. Any other use or use beyond these limits is assumed unintended.

⚠ WARNING

Danger caused by unintended use!

Dangers may arise from the unit if it is put to unintended use and/or if it is used for any other purposes.

- ▶ Only use the unit *for* the purpose it is intended for.
- ▶ Follow the procedures described in these operating instructions.

Claims of any type because of damages resulting from unintended use are excluded.

The user is the sole bearer of the risk.

2.2 Personnel requirements

NOTE

- ▶ Work on/with the unit must only be carried out by persons who are authorized for this work because of their education and qualification. Apart from this these persons must also be entrusted with this work by the operator.
- ▶ Allow personnel to be trained, instructed, directed or undergoing general training to only work on or with the unit under the supervision of an experienced person.
- ▶ Persons who are under the influence of drugs, alcohol or medication that affects their responsiveness may under no circumstances carry out work on or with the unit.
- ▶ Dangers may arise from the unit if it is improperly used by untrained personnel.
- ▶ All generally valid legal and otherwise binding regulations for the avoidance of accidents and the protection of the environment as well as general health and safety requirements must be observed in addition to the operating instructions. The operator must instruct his personnel accordingly.

2.3 General safety notes

NOTE

For safe handling of the unit you should comply with the following general safety notes:

- ▶ Do NOT operate the unit in the presence of explosive gases or in an explosion endangered environment.
- ▶ Before start-up check the proper condition of the unit (mains cable, housing, chamber, hoses, filter, etc.).
- ▶ Aerosol and ventilation hoses free of loops, creases and buckling.
- ▶ Stand the unit horizontally; inclination of the support area $\leq 3\%$.
- ▶ Do not cover the unit; the underside is provided with ventilation slots, the air intake for aerosol transport is located on the back of the unit.
- ▶ Ensure an adequate water level in the nebulizer chamber.
- ▶ Only aqueous solutions are permitted to be nebulized.
- ▶ Do not use any combustible fluids or carrier gases.
- ▶ Do not reach into the nebulizer chamber during operation.
- ▶ The nebulizer chamber must only be filled in assembled condition.
- ▶ Operate the unit only with an appropriate water level.
- ▶ Remove the nebulizer chamber only when the unit is switched off.
- ▶ After removing the nebulizer chamber the user should not touch the uncovered contacts on the unit for safety reasons.
- ▶ When removing the nebulizer chamber the user should never touch the uncovered contacts on the unit and the patient at the same time for safety reasons.

- ▶ The HICO-ULTRASONAT 810 is not intended for direct inhalation via mouthpiece or face mask. The distance between patient and aerosol hose should be at least 10 cm.
- ▶ Under hygienic aspects a cleaned, disinfected or (when using disposable products) new nebulizer system must be used when changing patients and/or nebulizer medium.
- ▶ Strictly comply with the ambient temperature range (10 - 30 °C) and storage temperature range (10 - 40 °C).
- ▶ An ambient temperature of 30 °C must not be exceeded when operating with a heated aerosol hose (danger of too high aerosol temperature).
- ▶ The unit must only be operated with original HICO accessories and an original bacteria filter.
- ▶ In operation do not use or combine the unit with other heat sources, which may be available as accessories.
- ▶ Do not operate the unit in the vicinity of heat sources (spotlights, direct insolation, radiators/ radiant heaters, etc.).
- ▶ Perform maintenance and operation related inspections by following these operating instructions.

2.4 Danger sources

2.4.1 Danger of drowning

▲WARNING

There is a risk that the patient may drown.

- ▶ In case of too direct and too long aerosol administration the patient may suffer under drowning symptoms. Monitor the type and duration of administration when using the unit on a patient.
- ▶ Maintain a minimum distance of approx. 10 cm between aerosol outlet and patient.

3 Transport and placement

3.1 Scope of delivery and transport inspection

The scope of delivery of the HICO-ULTRASONAT 810 for standard installation consists of:

- HICO-ULTRASONAT 810 unit with mains cable
- nebulizer chamber with distance ring, cover and cone cup ring as accessory
- one ventilation and aerosol hose each
- bacteria filter, coarse air filter and angle adapter
- holding bar and supporting arm

The accessory optionally consists of:

- five-foot rack on castors for installation as a mobile unit
- wall bar holder for installation as wall unit
- bottle, bracket and level regulator for continuous nebulizing, permanent nebulization system
- disposable cone cups for drug nebulization
- heated aerosol hose
- silicone aerosol hose
- disposable aerosol hose
- heater for disposable aerosol hose

NOTE

- ▶ Check the delivery for completeness and visible damages.
- ▶ Immediately report an incomplete delivery or damage caused by inappropriate packaging or transport to the forwarding agent, the insurance company and the supplier.

3.2 Unpacking

To unpack the device:

- Take the unit out of its box and remove the packaging material.
- Stand the unit on a level and horizontal base with sufficient load bearing capacity.

3.3 Waste disposal of packaging material

The packaging material protects the unit against transport damage. The packaging material has been chosen under environmental and waste disposal related aspects and is therefore recyclable.



Returning packaging material to the material circulation system saves raw materials and reduces the amount of waste. Return packaging material, that is no longer needed, to the collecting locations for the recycling system in your country.

NOTE

- If possible keep the original packaging over the warranty period, to be able to pack the unit again properly in case of a warranty claim.

4 Commissioning

This chapter contains important information for commissioning the unit. Please follow these notes to avoid dangers and damages.

4.1 Safety notes

▲WARNING

Personal injuries and material damage may occur when commissioning the unit!

Please comply with the following safety notes to avoid dangers:

- ▶ The unit has form closed and moveable components. Avoid risks of crushing and shock when unpacking and setting up.

▲CAUTION

Follow the hygiene requirements!

- ▶ When setting up the unit make sure you use a sterile, new or cleaned nebulizer system, fresh filters (bacteria filter with CE-sign) and coarse air filter.

4.2 Placement and setting up

4.2.1 Requirements on the set up place

For safe and fault-free operation of the unit the set up place

- must have sufficient load bearing capacity (weight of unit approx. 4.5 kg).
- must be level.
- must be horizontal (inclination $\leq 3\%$).
- must have sufficient stability.
- must provide 20 cm space at the back of the unit.
- the room must be sufficiently ventilated.

The optionally available five-foot rack meets these prerequisites.

NOTE

- If the unit is not exactly horizontal, the aerosol intensity may be impaired.

⚠ CAUTION

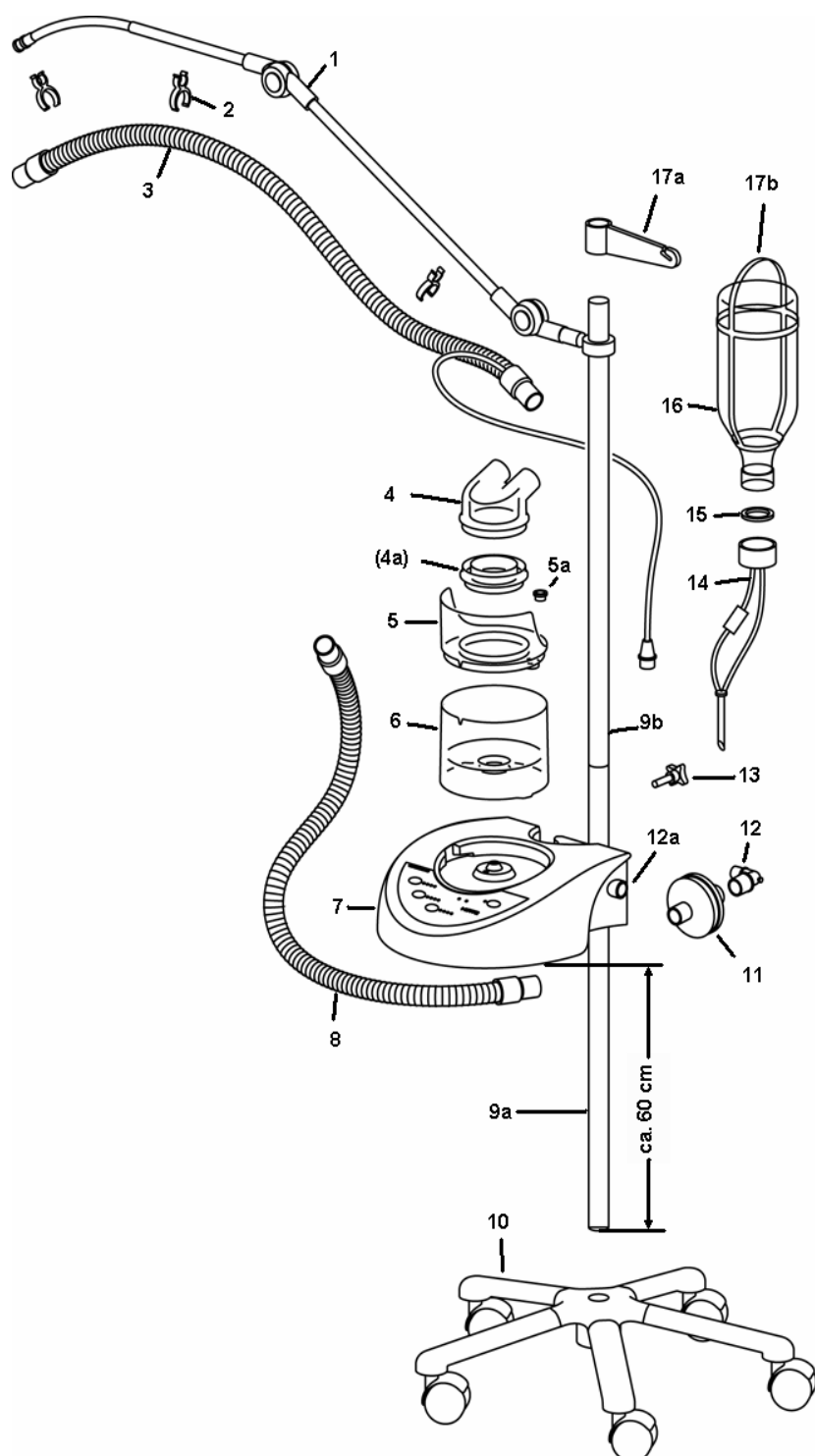
Personal injuries and material damage may occur when commissioning the unit!

- If the unit is not in a horizontal position, the oscillator may be damaged during dry running.
- Placing the unit too far away from the patient may impair the stability.

4.2.2 Illustration of device (standard setup of table unit)



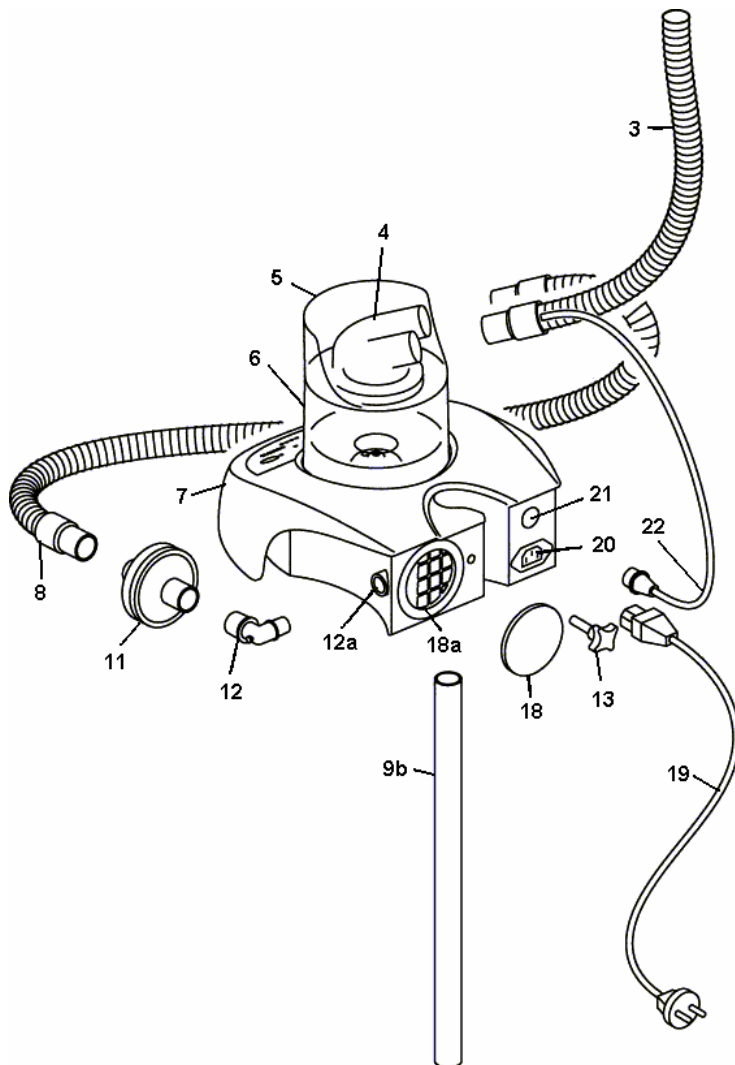
4.2.3 Total overview of components



1. Supporting arm
2. Clamps
3. Aerosol hose
4. Lid
- 4a. Cone cup ring (optional)
5. Distance ring
- 5a. Plug
6. Nebulizer chamber
7. Device
8. Ventilation hose
- 9a. Holding bar with thread
- 9b. Holding bar with dummy plug
10. Five foot on castors
11. Bacteria filter
12. Angle adapter
- 12a. Adapter connection
13. Grip screw
14. Level regulator
15. Gasket
16. Provision bottle
- 17a. Bottle holder
- 17b. Bottle suspension

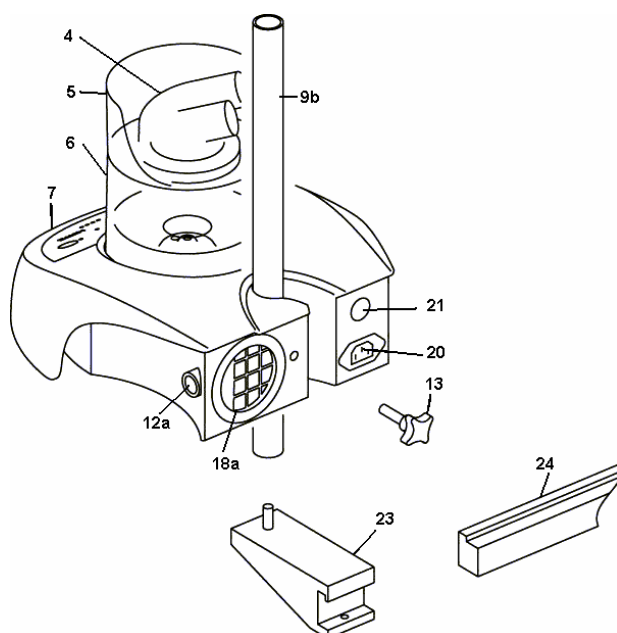
Total setup

(shown as standard unit including optional accessories)



- 3. Aerosol hose
- 4. Lid
- 5. Distance ring
- 6. Nebulizing chamber
- 7. Device
- 8. Ventilation hose
- 9b. Holding bar with dummy plug
- 11. Bacteria filter
- 12. Angle adapter
- 12a. Adapter connection
- 13. Grip screw
- 18. Coarse air filter
- 18a. Coarse air filter insert
- 19. Mains cable
- 20. Power inlet socket
- 21. Heating connection socket
- 22. Heating cable from aerosol hose (3)

Total setup rear view

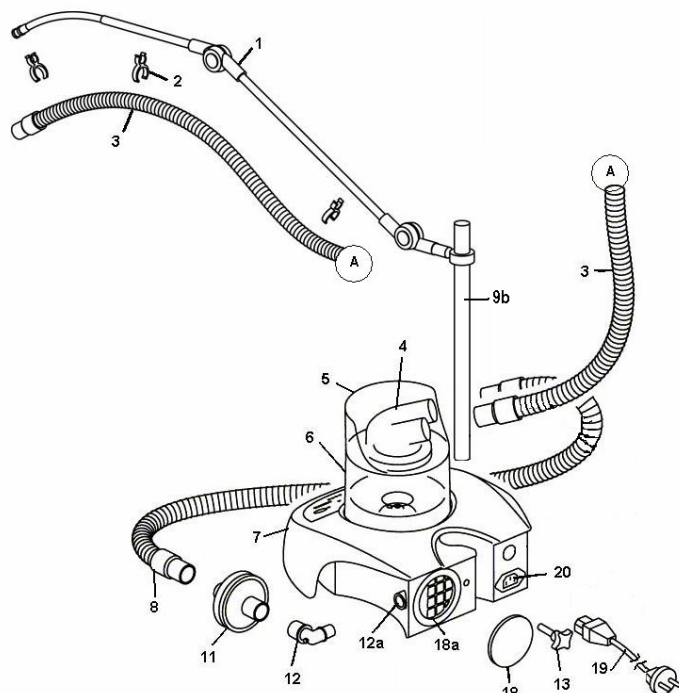


- 23. Wall bar holder
- 24. Wall bar

View as wall mounted unit

4.2.4 Standard setup as table unit

- a) Press the nebulizing chamber (6) with the distance ring (5) and the lid (4) slightly so that it engages in the bayonet lock of the device (7), then turn slightly clockwise against the stop.
- b) Insert the coarse air filter (18) into the corresponding recess (18a) on the device (7).
- c) Plug ventilation hose (8), bacteria filter (11) and angle adapter (12) together and connect the assembly to the adapter connection (12a) on the device (7). Route the ventilation hose along the front under the unit and connect it to the lid (4).
- d) Fasten the holding bar with blind plug (9b) to the device (7) using the grip screw (13). For reasons of stability the stand should touch the ground.
- e) Fasten the supporting arm (1) for the aerosol hose (3) on the holding bar with thread (9b) using clamping ring and grip screw (13).
- f) Use clamps (2) to fasten the aerosol hose (3) on the supporting arm.
- g) Insert the end socket of the aerosol hose (3) into the second opening of the lid on the nebulizer chamber (6), making sure that the supporting arm (1) is adjusted in such a way, that the aerosol hose (3) always remains stretched and has a continuous descent towards the nebulizer chamber (6), so that the condensed mist will flow back into the nebulizer chamber (6),
- h) Plug the mains cable into the unit and into a wall socket. The unit is ready for operation. This is indicated by the flashing LED to the left of the start button.



4.2.5 Setting up with five-castor base (optional)

The five-foot rack on castors, which is optionally available as an accessory, makes the stationary HICO-ULTRASONAT 810 mobile.

Set up the unit together with the five-foot rack as follows:

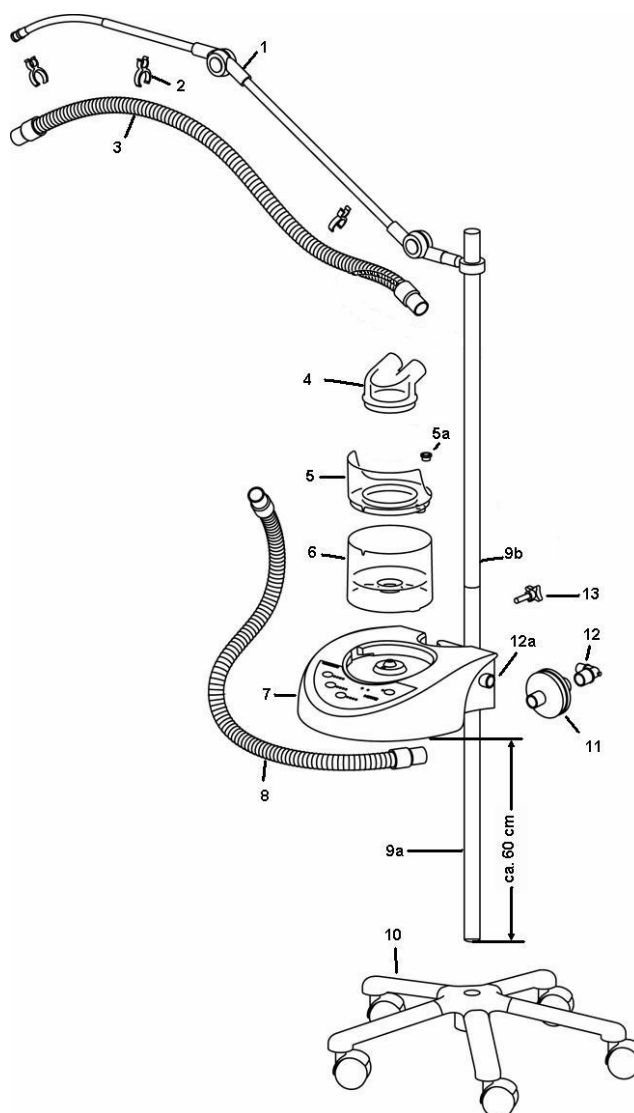
- a) Assemble the five-foot rack with the holding bar with thread (9a), as described in these assembly instructions.
- b) Screw the holding bar with blind plug (9b) to the holding bar with thread (9a) of the five-foot rack (10).
- c) Fasten the device (7) to the holding bars (9a/b) with the grip screw (13) (max. distance from floor 70 cm).
- d) Press the nebulizer chamber (6) with the distance ring (5) and the lid (4) slightly so that it engages in the bayonet lock of the device (7), then turn slightly clockwise against the stop.
- e) Insert the coarse air filter (18) into the corresponding insert (18a) on the device (7).
- f) Plug ventilation hose (8), bacteria filter (11) and angle adapter (12) together and connect the assembly to the adapter connection (12a) on the device (7). Route the ventilation hose along the front under the unit and connect it to the lid (4).
- g) Fasten the supporting arm (1) for the aerosol hose (3) on the holding bar with blind plug (9b) using clamping ring and grip screw.
- h) Use clamps (2) to fasten the aerosol hose (3) on the supporting arm (1).
- i) Insert the end socket of the aerosol hose (3) into the second opening of the lid on the nebulizer chamber (6), making sure that the supporting arm (1) is adjusted in such a way, that the aerosol hose (3) always remains stretched and has a continuous descent towards the nebulizer chamber (6), so that the condensed mist will flow back into the nebulizer chamber.

- j) Plug the mains cable into the unit and into a wall socket.
The unit is ready for operation. This is indicated by the flashing LED to the left of the start button.

▲ CAUTION

Personal injuries and material damage may occur when commissioning the unit!

- To guarantee a safe function and for a stable fixed stay bar (2) it is necessary that during the assembly of the five foot rack:
 - all 5 punches of the metallic disc lock into the wholes of the five foot extension,
 - the screw must be tighten strong by min. 9Newton m.
 These 2 phases must be checked direct after the assembly of the five foot rack and regularly during the running time.
- With respect to the stability of the complete equipment the distance between unit and floor should not exceed approx. 70 cm! (approx. the height of the screw connection 9a/9b).



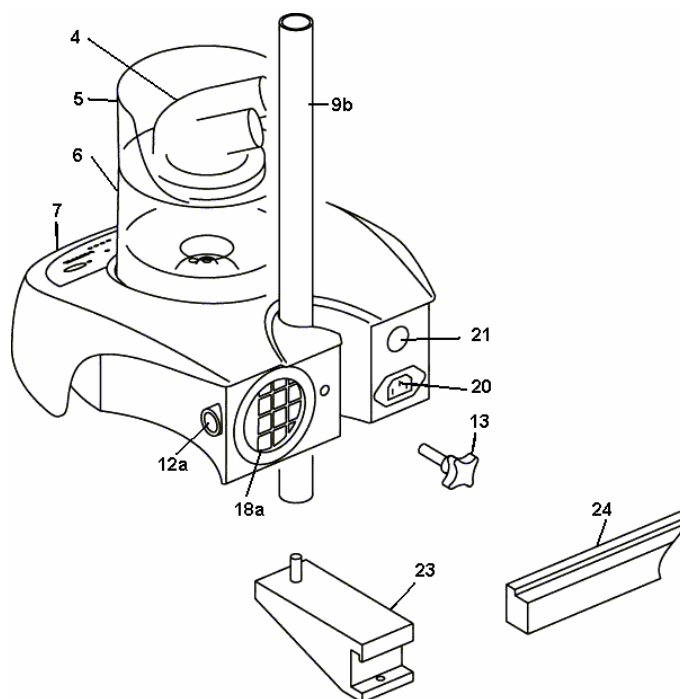
4.2.6 Use a wall rail unit (optional)

With the optionally wall bar holder the HICO-ULTRASONAT 810 can be mounted accordingly.

With the wall bar holder set up the unit as follows:

- a) Hook the wall bar holder (23) into the wall bar (24) and fasten it.
- b) Screw the holding bar with blind plug (9b) onto the wall bar holder
- c) Fasten the device (7) to the holding bar with blind plug (9b) using the grip screw (13), so that the device (7) rests on the wall bar holder.

Continue with point – d – in chapter 4.2.5.



4.3 Connecting the HICO-ULTRASONAT 810

⚠ WARNING

Danger caused by water in connection with electricity.

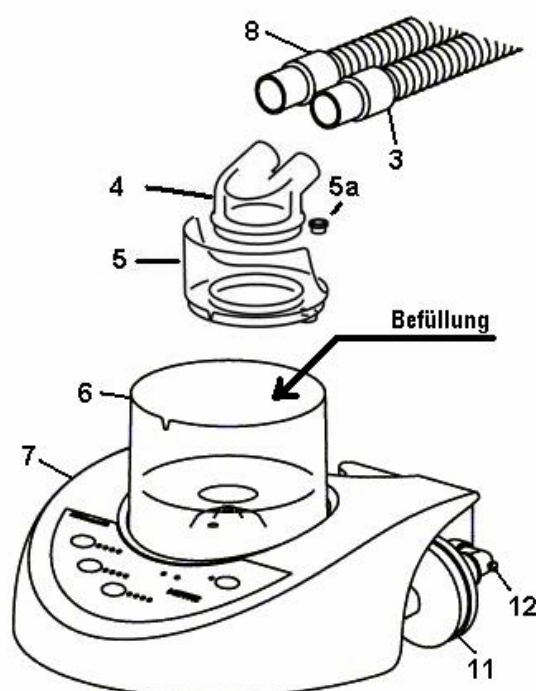
- Only connect the unit to the mains supply after it has been filled.

4.3.1 Filling the chamber / direct nebulizing

- Take the distance ring (5) with the lid (4) off the nebulizer chamber (6) and only fill the mounted nebulizer chamber (6) with the fluid intended for the patient.
- Place the distance ring (5) with plug (5a) and lid (4) back on the nebulizer chamber.
- Plug the ventilation and aerosol hoses (8/3) on the lid (4).
- Plug the mains cable into the unit and into a wall socket. The unit is ready for operation. This is indicated by the flashing LED to the left of the start button.

NOTE

- For appropriate nebulizing the filling quantity should be min. 125 ml and max. 620 ml.
- The level controller opening in the distance ring (5) must be closed with the plug (5a).



⚠ WARNING
Danger caused by water in connection with electricity.

Water is electrically conductive.

- ▶ The nebulizer chamber must only be filled in assembled condition.
- ▶ If water has been spilled when filling the unit, the unit must first be thoroughly dried and should only be connected to the mains supply and switched on after it has completely dried.

⚠ WARNING
Danger caused by the use of unsuitable media.

- ▶ Only aqueous solutions¹ are permitted to be nebulized.
- ▶ Do not use any combustible fluids or aerosol carrier gases.
- ▶ The user is solely responsible for any risks and side effects for the patient, which may result from the nebulized medium.

NOTE

- ▶ In direct nebulization the filled in quantity in the chamber is nebulized, until the dry running protection switches off the unit >> fault indication.

¹ Sterile water should commonly be used. Boiled tap water may also be used. The water quality (e.g. water hardness) and the admission of any type of additives may adversely affect the lifetime of water contacting equipment components.

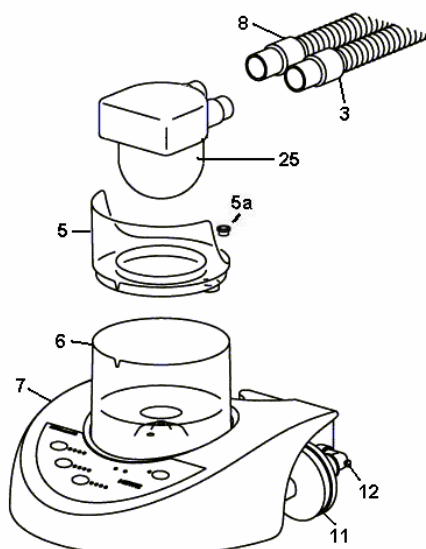
4.3.2 Nebulization using sterile water capsules

The HICO-ULTRASONAT 810 can be operated with almost all sterile water capsules currently available on the market.

- Disconnect the aerosol (3) and ventilation hose (8) from the lid (4).
- Replace the lid (4) with a sterile water capsule (25) and insert it into the distance ring (5) as far as it will go. Close the level controller opening (14; see pnt. 4.3.3) in the distance ring (5) with the plug (5a).
- Fill the nebulizing chamber (6) with water, so the bottom bowl of the sterile water capsule (25) will be surrounded by water after it has been placed into the nebulizing chamber (6).
Nebulizing is only possible when the sterile water capsule (25) is submerged in the water (transfer medium) inside the nebulizing chamber (6).
- Remove the screw caps from the sterile water capsule (25) and plug on the aerosol hose (3) and ventilation hose (8).
- Plug the mains cable into a wall socket. The unit is ready for operation. This is indicated by the flashing LED to the left of the start button.

NOTE

- An empty sterile water capsule is **not** indicated by the red fault lamp on the unit.
- The application notes for sterile water systems must be strictly followed.
- Only sterile water systems carrying the CE-sign may be used.

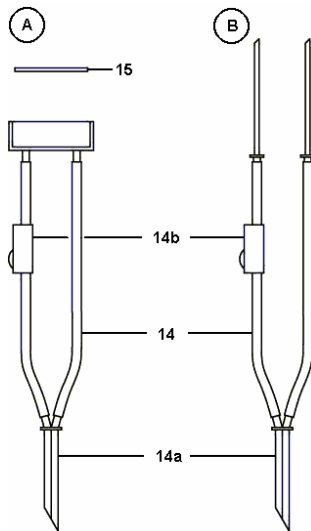


25. Sterile water capsule

4.3.3 Permanent nebulizing (optional)

The HICO-ULTRASONAT 810 can be fitted with a fluid container and level controller for permanent nebulizing.

- Fill the provision bottle (16) with the fluid intended for the patient (bottle with thread) or choose a ready filled bottle (bottles without thread). Prepare the fluid container with level regulator (14) as per a. or b.



a) **Level regulator for bottles with thread**

Screw the level regulator (14) with the bottle cap onto the filled bottle (16). Make sure that the gasket (15) is inserted in the bottle cap, the cap is screwed on tightly and the hose clamp (14b) is closed.

b) **Level regulator for bottles without thread**

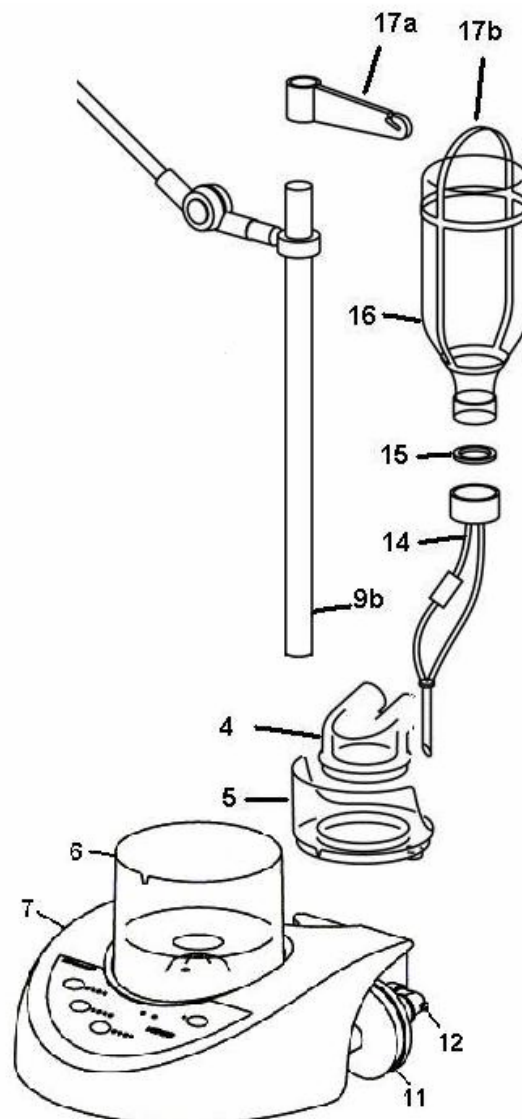
Penetrate the cannulas of the level regulator (14) through the rubber plug of the bottle (only once) and push in completely. Make sure that the hose clamp remains closed (14b).

- Mount the bottle holder (17a) to the holding bar with blind plug (9b) and tighten the grip screw to fasten.
- Fit the provision bottle (16) into the bottle suspension (17b), provide the level regulator (14) with the gasket (15) and hook the assembly to the bottle holder (17).
- Insert the level tube (14a) of the regulator (14) into the distance ring (5) of the nebulizing chamber (6).
- Attach the bottle (16) to the bottle holder (17a) and open the hose clamp (14b). The nebulizing chamber (6) fills up (approx. 600 ml). The level tube (14a) ensures that the fluid level inside the nebulizing chamber (6) will always remain constant, as long as the provision bottle (16) holds some fluid.

- Plug the mains cable into a wall socket. The unit is ready for operation. This is indicated by the flashing LED to the left of the start button.

⚠ CAUTION

- The provision bottle (16) must be made of glass or solid plastic material, as otherwise the function of the level controller will be impaired by vacuum. If the material of the dispenser bottle is too soft, it will give way resulting in uncontrolled emptying of the bottle and overflowing of the chamber.



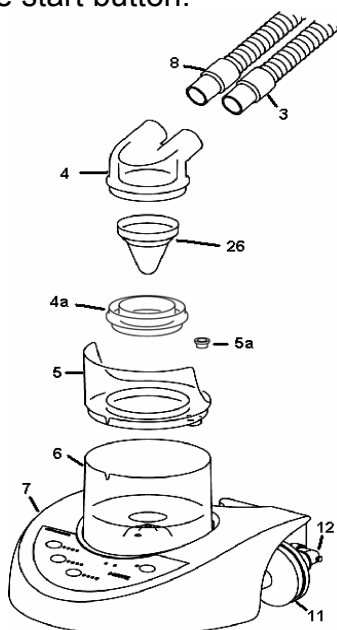
4.3.4 Lowest quantity nebulizing (optional)

With a special cone cup the HICO-ULTRASONAT 810 can be used for nebulizing smallest quantities of 5 ml to max. 15 ml.

▲ CAUTION

► Please follow the safety notes for nebulizing smallest quantities.

- Disconnect the aerosol (3) and ventilation hose (8) from the lid (4).
- Take off the cover (4) and insert the cone cup ring (4a) into the distance ring (5).
- Fill the nebulizer chamber (6) with approx. 550 ml to 600 ml water.
- Place the cone cup (26) into the cone cup ring (4a). Make sure that the cone cup (26) enters at least 1 to 2 cm into the water before the nebulizing medium (max. 15 ml) is filled in.
- Fill the cone cup (26) with the medium to be nebulized (max. 15 ml).
- Fasten the lid (4) by pressing it into the cone cup ring (4a), making sure that the cone cup (26) is plugged on the special recess on the underside of the lid (4).
- Plug the aerosol hose (3) and the ventilation hose (8) on the sockets of the lid (4).
- Plug the mains cable into a wall socket. The unit is ready for operation. This is indicated by the flashing LED to the left of the start button.



26. Cone cup

4a. Cone cup ring

NOTE

- ▶ Nebulizing is only possible when the cone cup (26) is penetrates into the water (transfer medium) inside the nebulizing chamber (6). The deeper it penetrates into the water, the better the transfer of nebulized medium.
- ▶ The cone cup ring in its function of filling and plugging in aid should be removed again for this purpose. The cone cup remains fastened to the lid.
- ▶ An empty cone cup is **not** indicated by the red fault lamp on the unit.

⚠ CAUTION

Safety notes for nebulizing smallest quantities.

- ▶ Before using the agent for nebulizing smallest quantities you must strictly read the user information provided by the manufacturer of the drugs and have the dosage determined by an authorized person or the treating physician.
- ▶ The user is solely responsible for any risks and side effects for the patient, which may result from the nebulized medium used for small quantity nebulizing.
- ▶ Only aqueous solutions must be used.
- ▶ The max. filling capacity of the cone cup (26) of 15 ml must not be exceeded.
- ▶ The duration, quantity and intensity of inhalation must be determined and monitored by an authorized or the treating physician.
- ▶ The cone cup (26) is a disposable product and must therefore only be used for one inhalation session (application) and one patient.
- ▶ Due to their chemical properties the nebulizing chamber (6) and the cone cup (26) as well as the aerosol and ventilation hoses (3 / 8) are not suitable for nebulizing ethereal oils, ketones, carbon hydrogens and various solvents, such as e.g. cyclohexanone resin, dimethyl sulphoxide, tetrahydrofuran.

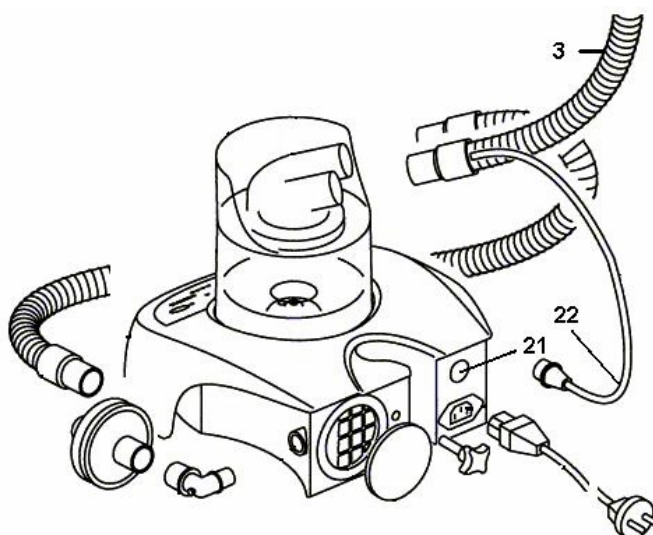
4.3.5 Heatable aerosol hose (optional)

The heatable aerosol hose additionally warms up the outflowing aerosol.

- Set up the equipment as described under points 4.2.3 and 4.2.4.
- Use the clips (2) to fasten the aerosol hose (3) to the supporting arm (1) in such a way, that the end socket of the aerosol hose with the heating cable can be adapted to the lid (4) (4)
- Adapt the end socket of the aerosol hose (3) to the lid (4), making sure that the supporting arm (1) is adjusted in such a way, that the aerosol hose (3) always remains stretched and has a continuous descent towards the nebulizing chamber (6), so that the condensed mist will flow back into the nebulizing chamber.
- Connect the plug of the heater cable (22) on the aerosol hose (3) with the heater socket (21) on the back of the unit just above the mains socket (20).

NOTE

- The heater socket is only in function when it is connected. It supplies the heating coil in the aerosol hose with constant power, which ensures a aerosol transfer temperature to the patient of max. 41°C.



4.3.6 Disposable aerosol hose (optional)

⚠ CAUTION

- ▶ Only dedicated hoses with approval for medical applications must be used.

When using a disposable aerosol hose you should proceed as described under 4.2.4. Only the standard aerosol hose is replaced.

4.3.7 Heating for disposable aerosol hose (optional)

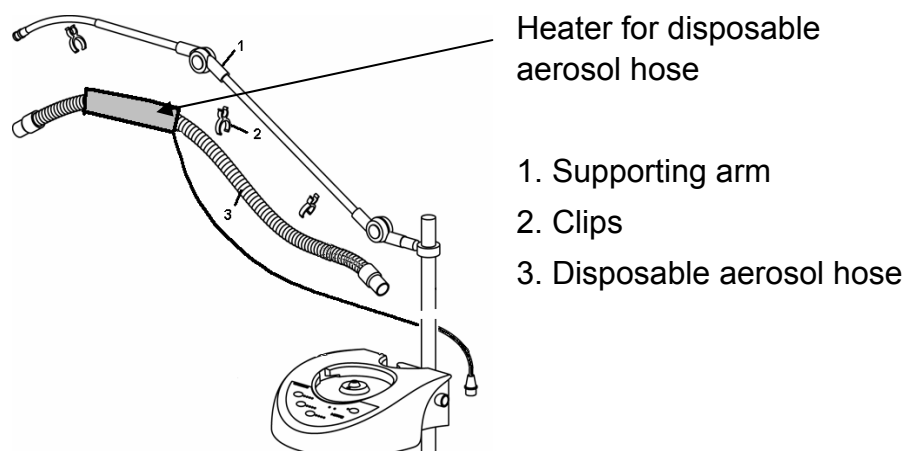
The heating for the disposable aerosol hose is a heating tube where the disposable aerosol hose (3) is pushed through. The disposable aerosol hose (3) is fastened to the carrier arm with clips (2) so that the heating tube covers the upper quarter of the disposable aerosol hose.

⚠ CAUTION

- ▶ The heating for the disposable aerosol hose is also heats up the outer insulation covering!
- ▶ Do NOT operate the heating for the disposable aerosol hose in the presence of explosive gases or in an explosion endangered environment!
- ▶ The heating for the disposable aerosol hose is solely a accessory for the HICO-ULTRASONAT 810!

NOTE

- ▶ The heating will only work when connected. (See heated aerosol hose).



4.3.8 Electrical connection

⚠ CAUTION

Danger caused by electric current

Defective cables and/or plugs can cause life threatening electric shock!

- ▶ Check the condition of unit cable and plug before connecting!

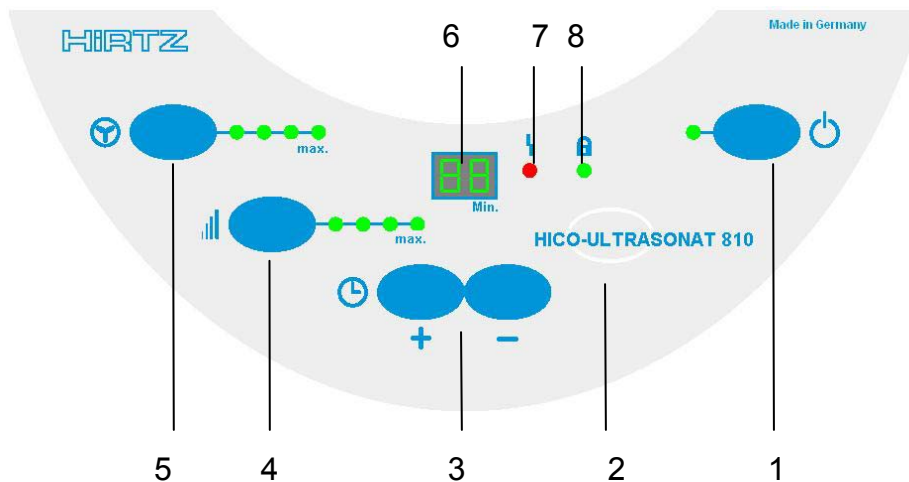
Please observe the following notes when connecting the unit electrically to ensure safe and fault free operation:

- Before connecting the unit compare the electric data (voltage and frequency) on the type plate with the data of your mains supply. These data must conform, so that damage to the unit is ruled out.
If in doubt, consult your electrics expert.
- The electric socket must be protected by a 16A circuit breaker.
- Use the cable supplied with the unit to connect the unit to the mains supply. The appliance connector is located on the back of the unit (see under point 4.2.3 Total setup rear view or under point 5.1).

5 Representation and function

This chapter contains important information about the design and function of the unit.

5.1 View of unit, control and display elements



- (1) Button On / Off (Start button)
- (2) Button to lock buttons (hidden)
- (3) Buttons for time setting of timer + / - (Start button for sole timer operation)
- (4) Button for nebulization, display of nebulizing intensity
- (5) Button for ventilation, display of ventilation intensity
- (6) Display of timer setting
- (7) Error display
- (8) Button lock display



Rear view (detail)
of the unit socket

5.2 Safety features

5.2.1 Sensors

During operation the HICO-ULTRASONAT 810 monitors

- the water level in the chamber (dry running protection)
- whether power transfer to the chamber is enabled
- whether mains voltage is applied
- whether the function is safe

and displays alarms in case of malfunctions.

The aerosol heating facility only works when the unit is connected accordingly and is in operation. The power output of the unit and the utilization of this output is technically limited.

5.3 Type plate

The type plate with the connection and performance data of the unit is located on the back of the unit:



The type plate with the connection and performance data of the heating for disposable aerosol hoses is located on the corresponding housing.



5.4 Function

5.4.1 Basics

The HICO-ULTRASONAT 810 works with a max. frequency of 1.7 MHz and a HF-output power of approx. 32 W. A piezo-ceramic oscillator (transducer) converts the electrical energy into mechanical energy. The resultant oscillations atomize the fluid inside the nebulizer chamber into smallest particles with a size of 0.5 to 6 µm. After the unit has been started, the oscillator (transducer) needs approx. 15-20 seconds for automatic calibration. No settings can be made during this time.

A bacteria filter (original with CE-sign) between fan and nebulizer chamber ensures germ free aerosol. The atomized fluid is fed to the area of the patient's respiratory organs (no direct inhalation!) through an aerosol hose.

With an aerosol heating (by means of, among others, heatable aerosol hose from the accessory program) the atomized fluid, the aerosol, can also be heated. In heatable aerosol hoses a plastic insulated heating wire is integrated in the aerosol hose in form of a spiral. The heating system for disposable aerosol hoses consists of a heating mat, which is fitted into a tube. At room temperature (max. 30°C) and with lowest air quantity the aerosol at the end of the hose is max. 43°C. The heating only works if the plug on the hose is plugged into the corresponding standard socket on the unit and only when the unit is in nebulizing operation, i.e. when the unit is functioning.

The HICO-ULTRASONAT 810 is characterised by simple and safe use, reliability and compact design.

The electronic control enables aerosol generation in continuous operation utilizing the complete chamber filling and in timer operation the duration of nebulizing can be set exact to the minute up to a time of 99 minutes.

Operation of the HICO-ULTRASONAT 810 is simple and intuitive, incorrect use is almost ruled out.

5.4.2 Indications / contraindications / side effects

With the following illnesses the guidelines issued by the Aerosol Therapy Guidelines Committee indicate the necessity of inhalation therapy:

- inflammation of the upper respiratory tract
- local anaesthesia in case of endoscopic operations
- rhinitis
- systemic illnesses

The HICO-ULTRASONAT 810 is used for clinical and therapeutic applications, normally in

- surgery - pre and postoperative to prevent infections (pneumonia prophylaxis)
- intensive care - respiratory air humidification
- internal medicine - specific and unspecific pulmonary illnesses, pneumonia, spasmodic asthma, bronchiectasis, acute, chronic and supra-infected bronchitis
- pediatrics - mucoviscidosis, pseudocroup, pneumonia, bronchitis
- otorhinolaryngology - respiratory air humidification (tracheotomy), laryngitis
- balneology - due to the improved dosing better application and efficiency in classical indication

for diagnostic use:

- pulmonology - stimulation aerosol application

We are currently not aware of any contraindications concerning the HICO-ULTRASONAT 810.

CAUTION

In small quantity nebulizing you must also follow the instructions (dosage, contraindications, side effects) issued by the corresponding medium manufacturer, in addition to these operating instructions. In dependence on the nebulized medium the inhalation may in this case

- ▶ cause bronchial spasm!
- ▶ lead to the elimination of the retching reflex, to allergic reactions and excessive systemic side effects!
- ▶ lead to a rebound of symptoms after the end of the therapy!

CAUTION

concerning safety in application

- ▶ The inhalation solution must be suitable for ultrasonic nebulizing!
- ▶ The inhalation solution must be used by following the instructions!
- ▶ Nosocomial infections may be caused by contaminated nebulizers!

6 Control and operation

This chapter contains important information for operation of the unit. Please follow these notes to avoid dangers and damages.

6.1 Before switching on

6.1.1 Inspections on the unit

- Examine the unit for any external damage.
- Examine the unit for correct assembly and setup.
- Only connect original HICO accessories to the HICO-ULTRASONAT 810.

NOTE

Before starting operation ...

- ▶ ... you must always ensure a sufficient filling level in the nebulizer chamber!
- ▶ ... you must make sure that a sterile (new, disposable or cleaned) nebulizer system is used when changing patients or nebulizing medium.
- ▶ ... the bacteria filter ((11) with CE-sign) should not have worked for longer than 50 hours and the coarse air filter (18) not more than 100 hours, depending on the operating environment (alternatively: bacteria filter one week, coarse air filter two weeks).

If in doubt, you should change the filters!

6.2 Operation

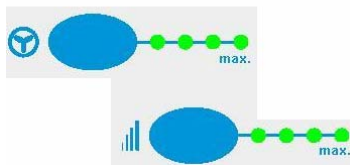
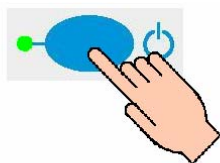


Once the system has been set up for the desired application and the mains cable of the unit has been plugged into a wall socket, the unit is ready for operation. This can be recognized by the flashing LED to the left of the start button (1).

NOTE

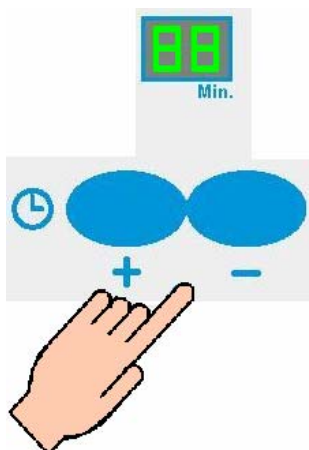
The unit will start work approx. 15 seconds after it has been switched on (time required for automatic calibration). Further settings are only possible after this time has expired.

6.2.1 Commissioning



- Press the start button (On / Off button (1)).
- The LED to the left of the start button, that was previously flashing, now lights permanently.
- The LED indicators for ventilation and nebulizing intensity light permanently in the previously made setting (25%-100% intensity).

6.2.2 Timer operation



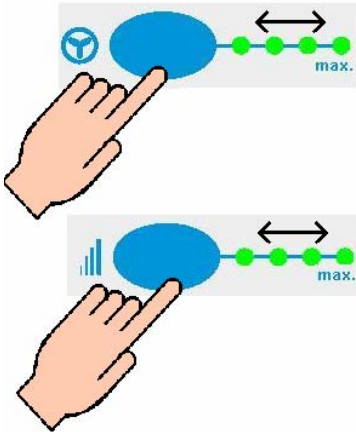
- Once the unit started operation you can select "Timer operation" by pressing one of the timer buttons (3 +/-) once.
- The time setting display (6) lights up and the time set last is displayed.
- The desired nebulizing time can be set from 1 minute to 99 minutes by pressing the timer buttons (3) for "+" or "-" as often as required.

Once the set nebulizing time has expired, the unit will automatically switch off. (Watch the filling level!)

NOTE

Timer operation can also be directly started via the timer buttons and switched off again with the "-" button (reset time to 0) (single button operation).

6.2.3 Adjusting flow and intensity



- If the system is working in the desired mode (approx. 15 seconds after starting), the air quantity, the flow, can be adjusted by operating the "Fan" button (5) as often as required.
- If the system is working in the desired mode (approx. 15 seconds after starting), the air aerosol intensity (aerosol density) can be adjusted by operating the "Nebulizing" button (4) as often as required.

NOTE

- ▶ In both settings the corresponding intensity is the higher, the more LEDs are permanently on.
- ▶ Adjusted intensities are saved after approx. 5 seconds and are maintained when the unit is switched off or disconnected from the electric power supply.

6.2.4 Button lock



The button (2) "Button lock" allows you to lock the adjusted intensities for flow and nebulization against de-adjustment.

This button is located below the product designation and can be identified by embossing in the button foil.

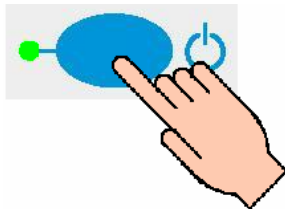
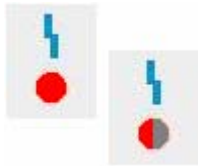
Once the desired intensities have been set and these settings are to be protected against de-adjustment, you must operate the button (2) "Button lock" for approx. 4 seconds.

When the button lock is activated the green LED (7) for button lock indication below the key symbol will light up.

NOTE

- ▶ For deactivation one must hold the button depressed for 4 seconds.
- ▶ The possibility for timer settings and operation mode (permanent or timer nebulizing) are not locked.

6.2.5 Alarm function



If a fault occurs during operation of the unit, e.g. filling level in chamber too low (dry running), electric power supply to oscillator interrupted or overloading, the unit will automatically switch off and the red LED (8) for fault indication lights permanently or flashes.

The unit needs to be switched off by the start button (1) to switch off this one and only alarm message.

The fault needs to be rectified before the start button (1) is pressed again to restart the system. Otherwise another alarm message will appear after a short while.

7 Cleaning and disinfection

This chapter contains important information about the cleaning and disinfection of the unit. Please follow these instructions to avoid damage caused by incorrect cleaning of the unit and to assure trouble-free operation.

7.1 Safety notes

▲ CAUTION

Observe the following safety notes before starting to clean the unit.

- ▶ Pull out the mains plug before starting cleaning and disinfecting the unit.
- ▶ Prevent fluids from entering into the unit.
- ▶ Let the unit dry completely before switching it on again.

CAUTION

Sensitive surfaces / materials.

The surfaces and materials of unit, system components and accessories can be destroyed by using wrong cleaning agents and disinfectants.

- ▶ Use only disinfectants based on aldehydes, ammonium components or alcohols, which will not affect ABS-plastics as well as PVC and PU for all surfaces and parts.
- ▶ If possible do not use any phenol derivative based disinfectants, because these will shorten the lifetime of plastic materials.

7.2 Unit

7.2.1 Surface

If possible use decalcified water. Only wipe the unit with a damp cloth. For cleaning use only warm water (max. 50°C) with a mild commercial dish washer liquid. Wipe off again with clear water and wipe the unit dry with a cloth.

To disinfest the surface of the unit we recommend a wiping or area disinfection acc. to RKI- or DGHM-list² (e.g. Mikrocid from S&M or Sanosil from Sanosil). When using a disinfectant follow the instructions of the manufacturer.

Only switch on the unit after the disinfectant has evaporated completely.

CAUTION

Only wipe off the surface of the unit, do not spray. In case of contact with the chamber make sure that no rubbed off moisture gets inside the unit. This makes sure that the unit will not be damaged.

7.2.2 Filter

Use of the bacteria filter (11) with CE-sign is mandatory for reasons of hygiene. The bacteria filter should be replaced at the latest after 50 hours of operation. The coarse air filter (18) should not have more than 100 operating hours. Alternatively: Bacteria filter 1 week, coarse air filter 2 weeks.

☞ If in doubt, you should change the filters.

NOTE

A reduced aerosol discharge from the hose sockets allows the conclusion that the filter is contaminated.

² Robert-Koch-Institut; Deutsche Gesellschaft für Hygiene und Mikrobiologie
Lists available from mhp-Verlag, Wiesbaden

7.3 Attachments and accessories

The cleaning and disinfection described in this manual applies for nebulizing elements (4-6), permanent nebulization system (14-17), aerosol ((3) and ventilation hose (8), angle adapter (12) (see point 4.2.3 Total setup page 18)

Elements not mentioned must be treated in the same way as the surface of the unit.

Remove the transducer (quartz) from the nebulizing chamber (see following chapter). Possibly existing deposits on the transducer must be carefully removed with a blunt object, e.g. a wooden spatula. Please take care not to damage the coating of the transducer surface.

If possible use decalcified water. Wash off contamination from other parts mentioned above using water and applying slight pressure. For cleaning use only warm water (max. 50°C) with a mild commercial dish washer liquid. Wash off again with clear water and wipe the components dry with a cloth.

For disinfecting the surfaces we recommend an area disinfection by wiping, spraying or dipping acc. to RKI- or DGHM-list³. If deemed necessary by the user, you may subject the ventilation hose (8), the aerosol hose (3) and possibly also the dispenser bottle elements (14-17) to a dipping disinfection (e.g. Mikrozid from S&M or Sanosil from Sanosil). When using a disinfectant follow the instructions of the manufacturer.

CAUTION

- ▶ Components must only be put back into service after all disinfectant has evaporated.
- ▶ After disinfection all parts must be checked for damage, deformation and cracks, and should be replaced if necessary.
- ▶ The sterile water capsule (25) as well as the cone cup (26) and the disposable aerosol hose are only intended for one-time use.

³ Robert-Koch-Institut; Deutsche Gesellschaft für Hygiene und Mikrobiologie
Lists available from mhp-Verlag, Wiesbaden

8 Maintenance and technical inspection

This chapter contains important information for maintenance of the unit. Please follow these instructions to avoid damage caused by inadequate maintenance of the unit and to assure trouble-free operation.

8.1 General

We recommend the conclusion of a maintenance contract with HIRTZ & Co. KG. By concluding a maintenance contract you fulfil the requirements

- the Occupational Safety directive (in Germany BetrSichV BGV A3),
- the Medical Product Directive 93/42/EEC,
- the MPBetreibV,

all of which request regular technical inspection of the units

Furthermore, maintenance by our experts ensures maximum operational reliability and longevity of the unit.

CAUTION

Do not apply any other cleaning and decontamination methods than the ones recommended by HIRTZ & Co. KG.

Before introducing new methods check these together with HIRTZ & Co. KG.

Only this makes sure that the unit will not be damaged by this method.

8.1.1 Unit

- Check fan and ventilation slots on the underside of the unit for dirt, at the latest after 6 months. Dust deposits inside the unit will reduce the performance of the system. Have the dirt inside the unit cleaned out by a Service Engineer (Customer Service, Medical Engineering). Do not open the unit yourself.
- Make sure that the Customer Service or the Medical Engineer complies with the maintenance and safety related inspection intervals.

8.1.2 Filter change

Bacteria filter:

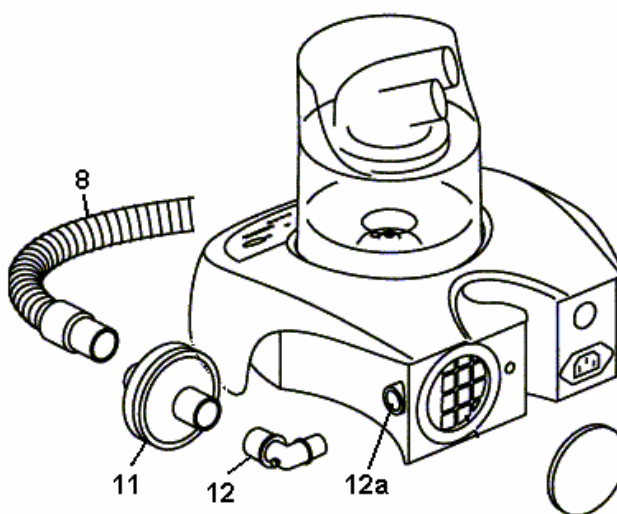
The bacteria filter (11) should be replaced at the latest after 50 operating hours (alternatively: 1 week).

This filter is inserted between angle adapter (12) and ventilation hose (8). The plugging direction cannot be mixed up by mistake because the connecting sizes are different.

NOTE

The unit must only be operated with an original bacteria filter, which should have at least the following properties:

- ▶ CE-sign,
- ▶ 99,93 % filtering effect (particle $\geq 0.3 \mu\text{m}$),
- ▶ 22 mm co-axial connections (ISO),
- ▶ Pressure differential $< 1 \text{ mbar}$ (50 l/min).



Coarse air filter:

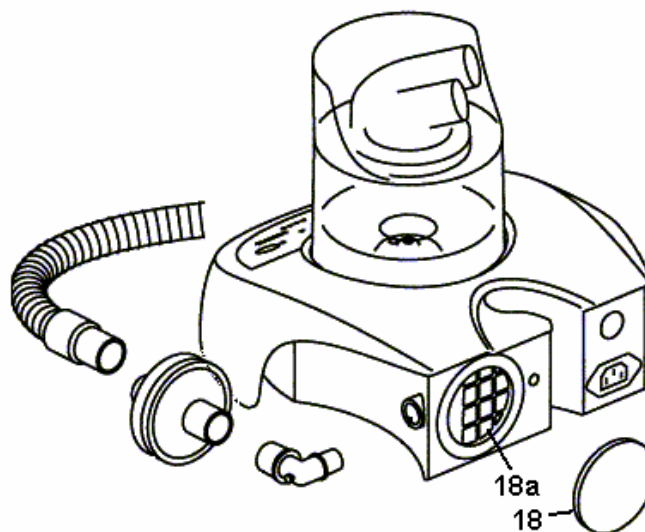
The coarse air filter (18) should not have more than 100 operating hours (alternatively: 2 weeks).

The **coarse air filter** (18) is pulled out of the the corresponding recess, coarse filter insert (18a), on the unit (7) and the new one is inserted with the coarse side facing outwards.

NOTE

The filter material should correspond with filter class EU 4 (B2/C) acc. to DIN 24185 and should at least have the following properties:

- ▶ Flow velocity 0.75 m/s,
- ▶ Nominal volume flow $2700 \text{ m}^3/\text{h} \cdot \text{m}^2$,
- ▶ Initial pressure differential 55 Pa
- ▶ Recommended final pressure differential 400 Pa
- ▶ Dust storage capacity 210 g.



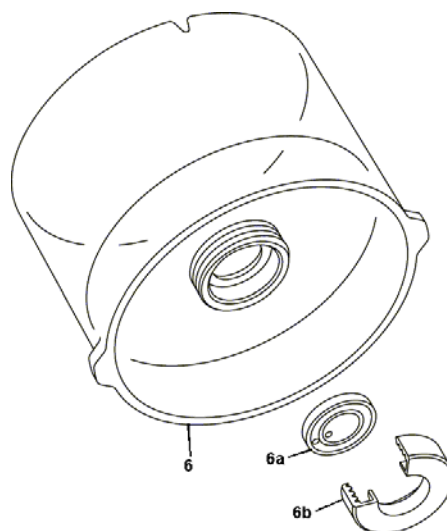
8.1.3 Transducer (quartz) replacement

The electronics of the HICO-ULTRASONAT 810 is designed in such a way, that changing the transducer does not require any new settings. This makes replacing the transducer very easy as follows:

- Disconnect the unit from the mains supply.
- Disassemble the nebulizing chamber (6) and extract the distance ring (5) with the cover (4) from the nebulizing chamber.
- Unscrew the cap nut (6b) underneath the bottom of the nebulizing chamber (6).
- Press the transducer (6a) with the seal out from inside.
- Assemble the new transducer with the seal so that the bright side faces the nebulizing chamber.
- Screw on the cap nut (6b) hand tight.

CAUTION

- ▶ Before mounting the nebulizing chamber to the unit fill the chamber with water to check for leaks. Incorrect assembly of the transducer will damage the unit.
- ▶ Using a non-original transducer will cause failure / damage of the unit and the loss of warranty.
- ▶ Only original HIRTZ spare parts may be used.



- 6. Nebulizing chamber
- 6a. Transducer (quartz)
- !! Here use **ONLY** original spare parts from Hirtz !!
- 6b. Cap nut

8.2 Technical inspection

In order to maintain legal conformity and operational reliability as per Medical Product Directive 93/42/EEC (appendix I, point 13.6.d) and MPBetreibV (§ 6(1)) the unit needs to be subjected to a safety related inspection every 12 months. The operator is solely responsible for the performance of this safety related inspection. Based on the MPBetreibV (§ 6 (4) 1.+3.) this safety related inspection must only be performed by HIRTZ & Co. KG or a qualified person. The safety related inspection covers at least the following points:

- Inspection of the device and application components for external damage, wear, aging and legibility of displays and inscriptions
- Measurement of the PE-resistance and the earth leakage current acc. to the testing facility and manufacturer's data
- Inspection of all functions by following the operating instructions
- Inspection of all safety functions acc. to manufacturer's data
- Inspection of all sensors acc. to manufacturer's data (for this purpose HIRTZ & Co. KG provides a Service Manual for authorized persons).

In order to maintain conformity with statutory safety regulations we recommend to conclude a Maintenance and Inspection Contract with HIRTZ & Co. KG. We will in this case carry out the annual regular inspections.

Questions concerning service, maintenance or technical inspection should be directly addressed to:

HIRTZ & Co. KG

Bonner Str. 180
50968 Köln / Germany
Phone: +49 (0)2 21 / 3 76 78-0
Fax: +49 (0)2 21 / 3 76 78-85
E-mail: hirtz@hico.de

9 Trouble shooting

This chapter contains important information for fault localisation and trouble shooting. Please follow these notes to avoid dangers and damages.

9.1 Safety notes

▲ CAUTION

- ▶ Repairs on electric devices must only be carried out by skilled professionals, which may have been trained by the manufacturer.
- ▶ Inappropriate repairs can cause considerable dangers for the user and damage to the unit.

NOTE

Opening of the unit by unauthorized persons will lead to the loss of any warranty claims.

9.2 Fault causes and rectification

The following overview should help to rectify possibly occurring minor faults.

Fault	Possible causes	Measures
The operation indication LED to the left of the start button does not flash and the unit is without function	Electric power supply interrupted	Check plug connection of mains lead and mains fuse (equipment fuse)
Operation indicator, Flow and Intensity LEDs light (1), flash (2), but no aerosol	1. Transducer 2. Fuse defective	1. Replace transducer 2. Replace the fuse (by medical engineering or customer service)
Red fault lamp lights continually	1. Lack of water 2. No contact between chamber and unit 3. Transducer defective	1. Fill up water up to min. 125 ml 2. Attach chamber with bayonet lock and lock properly 3. Replace the transducer
Red fault lamp flashes	1. Incorrect transducer 2. Mains voltage too low 3. Operating voltage for transducer not reached	1. Use only original HIRTZ spare parts 2. Inform the in-house electrician 3. Customer Service
Aerosol is generated, but does not reach the end of the hose	1. Filter clogged 2. Aerosol hose blocked by condensate 3. Fan defective	1. Replace the filter 2. Ensure return flow in the hose 3. Customer Service

NOTE

Both the mains fuse and the equipment fuse are installed on the printed circuit board inside the unit and must only be replaced with new fuse of the specified type (marked on the fuse type) by our Customer Service or a medical engineer authorized by HIRTZ, using appropriate tools.

10 Waste disposal of old unit



Old electric and electronic devices very often contain precious materials. However, they also contain harmful substances, which were necessary for their function and safety.

If disposed of as residual waste or handled incorrectly these can cause harm for human health and damage the environment. This device must **not** be disposed of with normal industrial or domestic waste!

NOTE

- ▶ According to the product reliability acc. to § 22 of the "Kreislaufwirtschafts- und Abfallgesetzes" (Recycling Economy and Waste Management Act) and the "Elektro- und Elektronikgesetzes" (Electrics and Electronics Act) § 2, section 1, cipher 8, the unit **must** be handed over to a corresponding communal collecting point or returned to the manufacturer

NOTE

- ▶ The components and accessories made of metal and plastic can be scrapped as domestic waste or incinerated according to the waste disposal instructions of the user.

11 Warranty

The HICO-ULTRASONAT 810 has been developed according to latest knowledge and is manufactured and tested by HIRTZ & Co. KG in strict compliance with highest technical standards.

However, should any defects occur during the period of 24 months starting with the date of purchasing by the end user, we guarantee free of charge replacement or free of charge repair of defects caused by material, design or production faults.

Warranty for the safety, reliability and performance of the unit can only be granted if:

- Assembly, new adjustments, modifications or repairs are carried out by HIRTZ & CO. KG or by authorized persons.
- **only** original parts (oscillator, transducer, etc.) are used,
- the unit is regularly serviced (filter change etc.),
- the electrical installation of the room fully complies with the requirements of IEC-determinations.
- the unit is used in full compliance with the operating instructions.

Under the following conditions, among others, warranty becomes null and void:

- damage caused by improper transport,
- damage caused by environmental effects
- damage caused by improper handling
- use of impermissible accessories

12 Technical data and accessories

12.1 Technical data

HICO-ULTRASONAT 810

Article-No. (REF):	390001
Rated voltage:	220-240 VAC // (110-120 VAC)* 50/60 Hz // (50/60 Hz)*
Power consumption:	approx. 85 W
Current consumption:	approx. 0.4 A // (approx. 0.8 A)*
Nebulizing performance	max. approx. 4.5 ml/min.
HF power output	approx. 32 W
Transducer frequency	up to about 1.7 MHz
Particle size	approx. 0.5 - 6 µm
Aerosol temperature	max. 43 °C
Ambient temperature	10-30 °C
Relative humidity	approx. 30.-70%
Storage temperature	10-40 °C
Air pressure	1013 hPa (+/-10%)
Class/type of protection:	I, B
Type of protection IP:	IP X1 (drip proof)
Risk class (93/42/EEC)	II a
Dimensions (W x H x D)	300 x 250 x 300 mm
Chamber capacity	max. 625 ml
Total height (with base)	approx. 1200 mm
Weight (unit standard setup)	approx. 4.5 kg
Weight cpl. (with packaging)	approx. 8 kg
Noise emission:	approx. 50 dB(A) (1 m)
Test basis:	Medical Product Directive 93/42/EEC, IEC 601-1, IEC 601-1-2
UMDNS-Code:	15-783

(Subject to change without notice)

* Set by the manufacturer in the unit as required by the customer. Observe the type plate!



The degree of electric protection in the application part corresponds with TYPE B.

Heating of disposable aerosol hose for HICO-ULTRASONAT 810

Article-No. (REF):	380316
Designation	Tube heater made of silicone, pre-formed for $D_i = 30 \text{ mm}$
Dimensions	250 x 94 x 2.5 (mm)
Voltage:	8 Volt, AC
Power:	14 W (resistive load)
Connection:	1 m silicone line 2 x 0.5 mm ²
Temperature sensor, limiter	without
Thermostat:	Switch-off temp. 70°C; Switch-on temp.: 40°C
Resistance	4.57 Ohm $\pm 5 \%$
Max. aerosol discharge temperature	41°C
Ambient temperature:	10-30 °C
Relative humidity	approx. 30.-70%
Storage temperature	10-40 °C
Air pressure	1013 hPa (+/-10%)
Type of protection IP:	IP 54

(Subject to change without notice)

NOTE

The HICO-ULTRASONAT 810 meets all requirements of classes A and B acc. to EN 55011. In class B the reception may be disturbed in case of out-of-band emission in the range of 1.67 MHz (above the medium wave band) when operating short-wave receiver stations in the immediate vicinity. For this case an additional net filter, which has been specially designed for the HICO-ULTRASONAT 810, is available. This filter, which has been specially adapted to the HICO-ULTRASONAT 810, is not suitable for other equipment and comes with the following technical data:

- ▶ Rated voltage: AC 110V / 230V
- ▶ Rated current: max. 2A
- ▶ Internal fuse: Fine fuse 5x20 - 2A slow blowing

12.2 Accessories

Only original HICO components and accessories may be used in connection with the HICO-ULTRASONAT 810 (necessary accessories). The required information to these parts can be found in these operating instructions and in the price list.

The accessory optionally consists of:

- five-foot rack on castors for installation as a mobile unit
- wall bar holder for installation as wall unit
- provision bottle, gasket, level regulator, bottle holder and bottle suspension as a permanent nebulization system
- cone cup and cone cup ring for drug nebulization
- heatable aerosol hose
- silicone aerosol hose
- disposable aerosol hose
- heater for disposable aerosol hose

13 Guidelines and declaration of manufacturer

Guidelines and declaration of manufacturer – electromagnetic emissions

Tables for electric medical equipment General information: - reduced version

Table 201

Line			
1	Guidelines and declaration of manufacturer – electromagnetic emissions		
2	The unit or system is intended for operation in an environment as described in the tables and texts of these operating instructions. The customer or user of this unit or system should make sure that it is actually operated in this type of environment.		
3	Interference emission measurements	Conformance	
4	HF-emissions Acc. to CISPR 11	Group 1	
6	HF-emissions Acc. to CISPR 11	Class B	
7	Emissions of harmonics acc. to IEC 61000-3-2	Class A	
8	Emissions of voltage fluctuations/flickering acc. to IEC 61000-3-3	Not applicable.	
9		[see 6.8.3.201 a) 3) and picture 201]	

Table 202

Interference immunity tests	IEC 60601-test level	Conformity level	
Electric static discharge (ESD) acc. to IEC 61000-4-2	±6 kV contact discharge ±8 kV air gap discharge	±6 kV contact discharge ±8 kV air gap discharge	
Quick transient electric disturbances/bursts Acc. to IEC 61000-4-4	±2 kV for mains lines ±1 kV for input and output lines	±2 kV for mains lines ±1 kV for input and output lines	
Surge voltages (surges) acc. to IEC 61000-4-5	±1 kV normal-mode voltage ±2 kV common-mode voltage	±1kV normal mode voltage ±2kV common mode voltage	
Voltage dips, short-term interruptions and fluctuations in the supply voltage acc. to IEC 61000-4-11	<5 % UT (>95 % dip in UT) for ½ period 40 % U (60 % dip in UT) for 5 periods 70 % UT (60 % dip in UT) for 25 periods <5 % UT (>95 % dip in UT) for 5 s	<5 % UT (>95 % dip in UT) for ½ period 40 % U (60 % dip in UT) for 5 periods 70 % UT (60 % dip in UT) for 25 periods <5 % UT (>95 % dip in UT) for 5 s	
Magnetic field in supply frequency (50/60 Hz) acc. to IEC 61000-4-8	3 A/m	3 A/m	

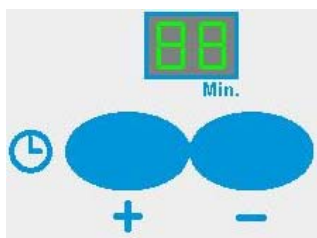
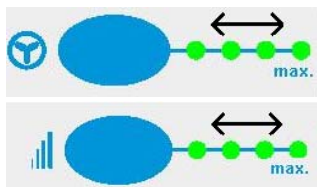
Table 204: NON life-supporting systems

Interference immunity tests	IEC 60601-test level	Conformity level	
Conducted HF-disturbances acc. to IEC 61000-4-6	3 V _{eff} 150 kHz to 80 MHz	3 V	
Radiated HF-disturbances acc. to IEC 61000-4-3	3 V _{eff} 80 MHz to 2.5 GHz	3 V/m	
Radiated HF-disturbances acc. to EN 60601-2-35	10 V/m	10 V/m	

Table 206: Electrical clearance to wireless telecommunication facilities

	Electric clearance depending on transmission frequency m		
Nominal power of transmitter W	150 kHz to 80 MHz $d = P \cdot \exp(0.5 \cdot 3.5 / V1)$	80 MHz to 800MHz $d = P \cdot \exp(0.5 \cdot 3.5 / E1)$	800 MHz to 2.5 GHz $d = P \cdot \exp(0.5 \cdot 7 / E1)$
0.01	0.12 m	0.12 m	0.24 m
0.1	0.37 m	0.37 m	0.74 m
1	1.17 m	1.17 m	2.34 m
10	3.69 m	3.69 m	7.38 m
100	11.67 m	11.67 m	23.34 m

14 Brief instructions



- Connect the unit to the mains supply.
- The green LED* to the left of the start button flashes. The unit is ready for operation.
- Fill the nebulizing chamber attached to the unit with the patient specific fluid quantity of 125 ml to 625 ml.
- Press the On / Off start button to start the unit.
- The previously flashing LED to the left of the start button as well as the green LEDs "Ventilation and nebulizing intensity indication", in their latest setting, will light permanently.
- After approx. 15 seconds (duration of automatic calibration) the unit will change to the indicated and adjusted operating status. Now the intensities can be changed.
- Press the fan button to set the desired air intensity (four stages indicated by LED)
- Press the nebulizing button to set the desired nebulizing intensity (four stages indicated by LED)
- For timer operation press one of the timer setting buttons. Press the buttons "+" or "-" to choose the operating time from 1 to 99 minutes. (Observe the filling level of the chamber!).
- Once the set time has expired, the unit will automatically switch off. (The LED to the left of the start button flashes, all others are off)

* LED-light >> Control lights / lamps; luminescent displays.

NOTE

These short instructions do not release the user from his/her obligation to thoroughly follow the operating instructions!

▲WARNING

There is a risk that the patient may drown.

- ▶ In case of too direct and too long aerosol administration the patient may suffer under drowning symptoms. Monitor the type and duration of administration when using the unit on a patient.
- ▶ Maintain a minimum distance of approx. 10 cm between aerosol outlet and patient.

▲CAUTION

Do not start the unit if

- ▶ there are damages and/or leaks,
- ▶ individual segments of the timer display have failed (operating time of the timer can no longer be read reliably),
- ▶ the red fault lamp (6) lights permanently,
- ▶ the unit does not respond to push button operation.

Notes
